



# COURAGE Chronicle

Courage Chronicle

August 1999



## CONGRATULATIONS TO THE FOLLOWING SUCCESSFUL COORDINATORS



Coordinator	Site	Patients Enrolled
Pat Baker	San Antonio – Audie Murphy VAMC	12
Cynthia Rowe	Houston VA Medical Center	7
Kendra Szymanski & Anita Bargardi	Ann Arbor VA Medical Center	7
Mary Jean Brewer	Nashville VA Medical Center	2
Karon Wagoner	Albuquerque VA Medical Center	2
Sandy Carr	London Health Sciences Centre	2
Peg Hanrahan	Seattle VA Medical Center	1
Lynne Shockey	Lexington VA Medical Center	1
Michele Costigan & Kathy Schneider	Iowa City VA Medical Center	1
Sara Hoffman	Durham VA Medical Center	1
Martha Castle	SUNY Health Science Center	1
Patty Eikenberry & Aimee Jacobs	Mid America Heart Institute	1
Kathy Comella & Dana Wade	Cleveland Clinic	1
Jan Richards	The Toronto Hospital	1
TOTAL PATIENTS ENROLLED: (AS OF 8/6/99)		40



### Tips For Enrollment Success

From Pat Baker, Study Coordinator, VAMC, San Antonio, TX

1. The ideal patients are those who just come out of a cardiology clinic before the stress test. In these cases, intervention has not yet been recommended and the coordinator can have some input in choosing a gated sestamibi (non-invasive) stress test.
2. Second choice is those patients in (a) the heart station, or (b) nuclear medicine with a positive stress test before intervention has been suggested. Trying to convince a patient to be randomized after an MD has indicated intervention is not very productive (for several reasons).
3. Third choice is patients coming out of the cath lab with diagnostic caths. Some movement in the decision process towards intervention may have already occurred.
4. Additionally, make daily rounds in the CCU and the telemetry units to review the charts. Talk to the nurses. In-services by the PI, SIs, and the coordinators are important!
5. Success in these four steps requires high activity levels, and personal contact with fellows and nurses is the key to success.
6. During the enrollment procedure, the coordinator and PI should be enthusiastic when talking to prospective study candidates about the trial. They should thoroughly explain the study including the benefits and risks associated with it.
7. The checklists prepared by West Haven are useful to organize and arrange the forms for the pre-randomization, baseline, and follow-up encounter with the patient. Include the appropriate PACE and MEDFICTS materials.
8. The patients generally like the Pentablot. Spend the time to instruct the patient how to answer the first one or two questions, asking the patient to demonstrate his/her ability to use the Pentablot. You then will have 45 minutes to one hour and 15 minutes to deal with another patient or make further arrangements for that patient.

## NOTES FROM WEST HAVEN

### **CRF ISSUES** (see Memorandum, July 30: Forms Submission to West Haven)

- \* All fully completed forms should be sent via Fed-Ex to West Haven **WEEKLY**. This includes Form 1 – Screening Log; however, you should not wait until all rows are complete before you send it. Send it along with the other CRFs **WEEKLY**.
- \* On Form 1 – Screening/Eligibility Log, remember to delete the column with the 'Creatinine' criterion. The 'Creatinine' criterion should not be used to check patient eligibility.
- \* If you cannot access the patient's SSN/SIN, use a sequential four digit number starting at 0001 for the screening number instead of the last four digits of the SSN/SIN. This is the screening number that you will subsequently record on each CRF.

### **RANDOMIZATION PROCESS**

- \* If patient is eligible and ready to be randomized, call West Haven. If the patient is scheduled to go to the Cath lab, the coordinator SHOULD call West Haven IN ADVANCE to alert of this imminent randomization (as per OPS Manual pp.2.12-14).
- \* When the patient goes in the cath lab and deemed angiographically eligible, the coordinator should take the next sequential envelope from the correct stratum (1=No Prior CABG/2=Prior CABG) and open it.
- \* Then the coordinator MUST call West Haven (at least by the next working day) in order to inform of the assignment for that patient.
- \* You should avoid placing a randomization call while the patient is on the table. Make the 'randomization alert' call PRIOR to patient taken to the cath lab.
- \* In the event that you cannot reach anybody at West Haven, you should take the next sequential envelope from the correct stratum, complete it and finally open the envelope to assign the patient to one of the treatments.

### **WHAT GOES WHERE??**

REFER TO THE [DOCUMENT, FILM & SPECIMEN DISPOSITION LIST DATED 8/10/99.](#)

# BEST WISHES NANCY!!!



Nancy Morgan from the Albuquerque Pharmacy Coordinating Center will be leaving at the end of August. We would like to take this opportunity to thank you Nancy for all of your hard work and dedication to this study. Best of luck in your future endeavors!!!

Carol Fye will be the pharmacist temporarily assigned to the study until a replacement is hired. Any questions or concerns should be directed to:

Jolene Day, Project Manager

PH: (505) 248-3203 FAX: (505) 248-3205

E-MAIL: [jolene.day@csp.research.med.va.gov](mailto:jolene.day@csp.research.med.va.gov)

## Operations Manual Subject Index

All coordinators were sent a subject index for the Operations Manual that was drafted by Paul Casperson. E-mail your comments about the index to Paul at: [paul.casperson@med.va.gov](mailto:paul.casperson@med.va.gov). The final version of the index will be sent out next month.

## Web Site Under Construction



The COURAGE Trial site is almost complete and will include the following: Welcome from Trial Leadership, a clickable site map indicating location, personnel and e-mail addresses, Message Board, FAQ, News and Events, Study Description, a page for our sponsors, a page with links of interest, and study documents will be available for viewing or downloading. Send any suggestions or ideas on how the site could be useful to you. If you see a web page you like, e-mail it along with your comments to Tenya Economou: [tenya@connix.com](mailto:tenya@connix.com) or FAX to: (203) 937-3858

**SLIDE SET AVAILABLE** PowerPoint 97 slide set is available from the kickoff meeting. Contact Dr. Pam Hartigan or Dr. William Weintraub if you would like to receive the zipped file. (WinZip can be downloaded free at: [www.winzip.com](http://www.winzip.com).)